

REMARKS

The Final rejection mailed January 30, 2009, has been carefully reviewed. Upon entry of the amendments presented above, the claims in the application will be only claims 19 and 23-26.¹ Applicants believe and respectfully submit that the claims define patentable subject matter and should be allowed. Favorable reconsideration and allowance are earnestly solicited.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Amended claim 19 recites a method for reducing the risk for developing cancer. The basis for this amendment is on page 18 line 17 (of WO01/078701), paragraph [0040] (of US publication 2004/0198674).

Amended claim 19 recites a method... comprising administering a composition... having... a carotenoid substantially devoid of provitamin A activity. The basis for this amendment is found at page 14, line 10 (of WO01/078701), paragraph [0039] (of US 2004/0198674).

¹ The withdrawn claims are deleted without prejudice to applicants' rights to pursue such claims and/or similar claims in a divisional application without any penalty whatsoever, applicants relying on §§121, 120 and 119.

The basis for newly added claim 23 is in previously presented claim 19. The basis for newly added claim 24 is in previously presented claim 20. The basis for newly added claim 25 is in previously presented claim 21. The basis for newly added claim 26 is in previously presented claim 22.

CLAIM REJECTIONS

35 U.S.C. § 103 Rejection

In the Office Action, the Examiner rejected claims 19-22 under 35 U.S.C. § 103(a), as being unpatentable over Jackson et al ("Jackson" or "the '586 Patent") in view of Schlipalius ("Schlipalius" or "the '790 Patent"). Applicants respectfully traverse this rejection.

Claim 19 has been amended to recite a method for reducing the risk for developing cancer associated with hormone replacement therapy (HRT) comprising administering to a woman in need thereof a unit dosage form composition daily, said unit dosage form composition having as active ingredients only at least one phytoestrogen and at least one carotenoid, wherein said carotenoid is substantially devoid of provitamin A activity.

The most relevant part of the '586 Patent (Jackson) discloses a dietary supplement composition and method for supplementing the dietary needs of a woman comprising

phytoestrogens in combination with vitamin A or carotenoids in lieu of vitamin A, but wherein the carotenoids must be selected among the approximately 50 "which can serve as precursors of retinol and therefore have provitamin A activity" (top of column 7). Jackson discloses that the amount of preformed vitamin A and/or mixed carotenoids in the compositions is in the range of about 200 to about 2000 μg RE. Several preferred provitamin A amounts are disclosed in retinol equivalents (RE), (column 7 lines 10-24). "Retinol equivalents" is a calculated value that represents the total retinol activity of a food or composition. Provitamin A has a fraction of the biological activity of retinol.

Thus, Jackson teaches the use of carotenoids having provitamin A activity, at least that of 200 μg . By detailing numerous RE amounts of carotenoids within the above mentioned range, Jackson is effectively teaching away from using carotenoids that are not within the specified range. Even more so, Jackson clearly leads the person of ordinary skill in the art away from using a composition having a carotenoid substantially devoid of provitamin A activity, as is required by amended claim 19.

Thus, claim 19 as amended is not disclosed nor is it suggested in the '586 Patent. Furthermore, Jackson clearly teaches away from amended claim 19.

Acknowledging that Jackson by itself does not reach applicants' invention, the PTO relies on Schlipalius as a secondary reference for the purpose of purportedly making it obvious to the person of ordinary skill in the art to use mixtures of lycopene, phytoene and phytofluene in the composition of Jackson. But Schlipalius has nothing to do with and cannot counteract the requirement of Jackson of the need for a certain minimum retinol activity. Whether or not Schlipalius is considered with Jackson, the person of ordinary skill in the art cannot practice Jackson while at the same time not fulfilling the Jackson requirement for provitamin A activity.

Schlipalius teaches a carotenoid composition and methods for producing the composition. The '790 Patent does not relate to a method for reducing the risk for developing cancer during hormone replacement therapy (HRT) or to compositions useful therein. The '790 patent does not relate to compositions combining phytoestrogens and carotenoids or to provitamin A activity of the carotenoids. As such, the '790 Patent does not cure the deficiency of the Jackson '586 Patent. Therefore amended claim 19 should be allowable over the Jackson '586 Patent in view of the Schlipalius '790 Patent.

In other words, the proposed combination would not have been obvious to the person of ordinary skill in the art, because the carotenoids mentioned by Schilipalius are not the types of carotenoids required by Jackson, i.e. they are not carotenoids which would provide the required retinol equivalents of Jackson.

Claims 23-26 are dependant from and incorporate the subject mater of claim 19 and are therefore likewise allowable over the proposed combination.

Although applicants no longer need to rely on the arguments previously presented, applicants do wish to respectfully make of record their disagreement with the position of the examiner as expressed under the heading "Response to Arguments" in the bottom paragraph on page 5 of the Final Action. The wording "substantially free of any other active component" means exactly that. There can be no confusion.

Applicants' believe that the law is clear that all recitations appearing in a claim must be given consideration and weight. When a claim says "substantially free of any other active component", it means that the claimed subject matter cannot contain any meaningful quantity of any component which is not mentioned in the claims, meaning that the

additional ingredients in Jackson remove Jackson from the subject matter being claimed, and it matters not in this regard whether the transitional phrase is "comprising" or one of the other open transitional terms. This also has nothing to do with any so-called negative effects.

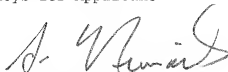
The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants respectfully assert that the present invention is new, non-obvious and useful. Favorable consideration and allowance of the claims are respectfully requested.

Respectfully submitted,

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